

Restriction Requirement Response  
Serial No. 10/612,784  
Docket No. ORW01-GN004

In the Claims:

1. A prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly adapted to be fastened to a patient's pelvis and a femoral stem adapted to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the constraining device comprising:

a semiannular augment adapted to be mounted approximate to a rim of an acetabular cup assembly of a hip replacement prosthesis, wherein the augment assists in improving stability, at least temporarily, of a ball joint type coupling between the acetabular cup assembly and a femoral stem of the hip replacement prosthesis;

the semiannular augment being formed from an augment material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

2. The prosthetic device of claim 1, further comprising at least one fastener for mounting the semiannular augment to the acetabular cup assembly, the fastener being formed from a fastener material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

3. The prosthetic device of claim 2, wherein the fastener material includes at least one, or an equivalent, of:

a poly-L-lactic acid material; and  
collagen.

4. The prosthetic device of claim 2, wherein the fastener comprises at least one of:

a screw;  
a snap;  
a clip;  
a keyway;

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a dowel; and

a rivet.

5. The prosthetic device of claim 1, wherein the augment material includes at least one, or an equivalent, of:

extra cellular matrices (ECMs);  
poliglecaprone 25;  
polydioxanone;  
surgical gut suture (SGS);  
gut;  
polyglactin 910;  
human autograft tendon material;  
collagen fiber;  
poly-L-lactic acid (PLLA);  
polylactic acid (PLA);  
polylactides (Pla);  
racemic form of polylactide (D,L-Pla);  
poly(L-lactide-co-D,L-lactide);  
polyglycolides (PGa);  
polyglycolic acid (PGA);  
polycaprolactone (PCL);  
polydioxanone (PDS);  
polyhydroxyacids; and  
resorbable plate material.

6. The prosthetic device of claim 5, wherein the extra cellular matrices (ECMs) include at least one of:

porcine small intestine submucosa (SIS);  
xenogeneic small intestine submucosa (xSIS);  
urinary bladder submucosa (UBS);

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laminated intestinal submucosa; and  
glutaraldehyde-treated bovine pericardium (GLBP).

7. The prosthetic device of claim 1, wherein a distal surface of the semiannular augment opposing a surface of the semiannular augment abutting the rim of the acetabular cup assembly is contoured to approximate the shape of a portion of the neck of the femoral component potentially coming into contact therewith.
8. The prosthetic device of claim 1, wherein the semiannular augment is positioned on an anterior/superior portion of the rim of the acetabular cup assembly.
9. The prosthetic device of claim 1, wherein:  
the femoral component includes a ball at its proximal end for mating with the acetabular cup assembly to form a ball-joint coupling; and  
the semiannular augment includes a contoured, radially inner surface to approximate an outer surface of the ball of the femoral component potentially coming into contact therewith.
10. The prosthetic device of claim 9, wherein the contoured, radially inner surface of the augment is substantially semi-spherically shaped.
11. The prosthetic device of claim 9, wherein the contoured, radially inner surface is substantially arcuate.
12. The prosthetic device of claim 1, wherein the semiannular augment is mounted to a proximal rim surface of the acetabular cup assembly.
13. The prosthetic device of claim 1, wherein the semiannular augment is mounted to a proximal rim surface of a cup-shaped bearing insert component of the acetabular cup assembly.

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14. The prosthetic device of claim 2, wherein the semiannular augment includes at least one integrated fastener.
15. The prosthetic device of claim 14, wherein the integrated fastener includes a snap-on retention member enabling snap-on-type mounting of the semiannular augment to the acetabular cup assembly.
16. The prosthetic device of claim 1, wherein the augment material is supplemented with an agent to promote the formation of scar tissue.
17. The prosthetic device of claim 1, wherein the augment material is supplemented with a clotting agent.
18. The prosthetic device of claim 1, wherein the augment material is supplemented with an antibacterial agent.
19. The prosthetic device of claim 1, wherein the augment material is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.
20. The prosthetic device of claim 19, wherein the augment material is adapted to be substantially absorbed and replaced by scar tissue within approximately 6 months after implantation.
21. The prosthetic device of claim 1, wherein the semiannular augment extends less than 360 degrees about the femoral stem.
22. The prosthetic device of claim 1, wherein the semiannular augment extends 180 degrees or less about the femoral stem.

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23. The prosthetic device of claim 1, wherein the semiannular augment extends 90 degrees or less about the femoral stem.

24. The prosthetic device of claim 1, wherein the semiannular augment extends 45 degrees or less about the femoral stem.

25. The prosthetic device of claim 1, wherein:

the femoral component includes a ball at its proximal end for mating with the acetabular cup assembly to form a ball-joint connection; and

the semiannular augment assists in constraining the ball within the acetabular cup assembly.

26. The prosthetic device of claim 1, wherein:

the femoral component includes a ball at its proximal end for mating with the acetabular cup assembly to form a ball-joint connection; and

the semiannular augment assists in restraining the ball within the acetabular cup assembly.

27. A hip prosthesis comprising:

an acetabular cup assembly adapted to be fastened to a patient's pelvis;

a femoral stem adapted to be fastened to the patient's femur, the femoral stem including a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling; and

a semiannular augment mounted to a distal end of the acetabular cup assembly, adjacent to the ball component, wherein the semiannular augment assists in stabilizing the ball joint type coupling between the acetabular cup assembly and the femoral stem;

the semiannular augment being formed from an augment material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

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28. The hip prosthesis of claim 27, further comprising at least one fastener mounting the semiannular augment to a distal rim surface of the acetabular cup assembly, wherein the fastener is formed from a fastener material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

29. The hip prosthesis of claim 28, wherein the fastener material includes at least one, or an equivalent, of:

- a poly-L-lactic acid material; and
- collagen.

30. The hip prosthesis of claim 28, wherein the fastener comprises at least one of:

- a screw;
- a snap;
- a clip;
- a keyway;
- a dowel; and
- a rivet.

31. The hip prosthesis of claim 27, wherein the augment material includes at least one, or an equivalent, of:

- extra cellular matrices (ECMs);
- poliglecaprone 25;
- polydioxanone;
- surgical gut suture (SGS);
- gut;
- polyglactin 910;
- human autograft tendon material;
- collagen fiber;

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poly-L-lactic acid (PLLA);  
polylactic acid (PLA);  
polylactides (Pla);  
racemic form of polylactide (D,L-Pla);  
poly(L-lactide-co-D,L-lactide);  
polyglycolides (PGa);  
polyglycolic acid (PGA);  
polycaprolactone (PCL);  
polydioxanone (PDS);  
polyhydroxyacids; and  
resorbable plate material.

32. The hip prosthesis of claim 31, wherein the extra cellular matrices (ECMs) include at least one of:

porcine small intestine submucosa (SIS);  
xenogeneic small intestine submucosa (xSIS);  
urinary bladder submucosa (UBS);  
laminated intestinal submucosa; and  
glutaraldehyde-treated bovine pericardium (GLBP).

33. The hip prosthesis of claim 27, wherein a distal surface of the semiannular augment is contoured to approximate the shape of a portion of the neck of the femoral component.

34. The hip prosthesis of claim 27, wherein the semiannular augment is positioned on the anterior/superior portion of the acetabular cup assembly.

35. The hip prosthesis of claim 27, wherein the semiannular augment includes a contoured, radially inner surface to approximate an outer surface of the ball of the femoral stem.

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36. The hip prosthesis of claim 27, wherein the contoured, radially inner surface of the semiannular augment is substantially semi-spherically shaped.
37. The hip prosthesis of claim 27, wherein the augment material is supplemented with an agent to promote the formation of scar tissue.
38. The hip prosthesis of claim 27, wherein the augment material is supplemented with a clotting agent.
39. The hip prosthesis of claim 27, wherein the augment material is supplemented with an antibacterial agent.
40. The hip prosthesis of claim 27, wherein the augment material is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.
41. The hip prosthesis of claim 40, wherein the augment material is adapted to be substantially absorbed and replaced by scar tissue within approximately 6 months after implantation.
42. The hip prosthesis of claim 27, wherein the semiannular augment extends less than 360 degrees about the femoral stem.
43. The hip prosthesis of claim 27, wherein the semiannular augment extends 180 degrees or less about the femoral stem.
44. The hip prosthesis of claim 27, wherein the semiannular augment extends 90 degrees or less about the femoral stem.

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45. The hip prosthesis of claim 27, wherein the semiannular augment extends 45 degrees or less about the femoral stem.

46. The hip prosthesis of claim 27, wherein the semiannular augment assists in constraining the ball within the acetabular cup assembly.

47. The hip prosthesis of claim 27, wherein the semiannular augment assists in restraining the ball within the acetabular cup assembly.

48. The hip prosthesis of claim 27, comprising a plurality of the semiannular augments mounted to the distal end of the acetabular cup assembly, adjacent to the ball component.

49. The hip prosthesis of claim 48, wherein a first one of the semiannular augment restrains the ball within the acetabular cup assembly and a second one of the semiannular augments is adapted to abut the femoral stem when the femoral stem pivots to a predetermined angle.

50. The hip prosthesis of claim 49, wherein the second semiannular augment is diametrically opposed to the first semiannular augment about the acetabular cup assembly.

51. The hip prosthesis of claim 27, wherein the acetabular cup assembly includes a cup-shaped bearing insert receiving the ball component of the femoral stem and the semiannular augment is mounted to a rim of the bearing insert.

52. The hip prosthesis of claim 51, wherein a first one of the semiannular augment restrains the ball within the acetabular cup assembly and a second one of the semiannular augments is adapted to abut the femoral stem when the femoral stem pivots to a predetermined angle.

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53. The hip prosthesis of claim 52, wherein the second semiannular augment is diametrically opposed to the first semiannular augment about the acetabular cup assembly.

54. A prosthetic constraining kit for implantation in proximity to a hip joint, comprising a plurality of constraining augments being adapted to be individually fastened on at least one of an acetabular prosthesis and about an acetabular cavity within a hip bone and circumferentially positionable about a femoral member taken from a group consisting of a femur and a femoral prosthesis, where the constraining augments at least partially define a central aperture allowing the femoral member to extend therethrough and allowing a range of angular motion of the femoral member while inhibiting a femoral head of the femoral member from completely passing distally through the central aperture.

55. The prosthetic constraining kit of claims 54, wherein the constraining augments comprise at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

56. The prosthetic constraining kit of claim 54, wherein the constraining augments are circumferentially positioned to define a ring.

57. The prosthetic constraining kit of claim 54, wherein at least two of the augments are spaced apart to define a discontinuous ring.

58. The prosthetic constraining kit of claim 57, wherein the discontinuous ring includes more than one discontinuity.

59. The prosthetic constraining kit of claim 54, wherein each constraining augment includes at least one fastener for mounting the augment to the distal rim surface of the acetabular cup assembly, wherein the fastener is formed from a fastener material selected

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from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

60. The prosthetic constraining kit of claim 59, wherein the fastener material includes at least one, or an equivalent, of:

a poly-L-lactic acid material; and  
collagen.

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61. The prosthetic constraining kit of claim 59, wherein the fastener comprises at least one of:

- a screw;
- a snap;
- a clip;
- a keyway;
- a dowel; and
- a rivet.

62. The prosthetic constraining kit of claim 55, wherein the material of the constraining augments includes at least one, or an equivalent, of:

- extra cellular matrices (ECMs);
- poliglecaprone 25;
- polydioxanone;
- surgical gut suture (SGS);
- gut;
- polyglactin 910;
- human autograft tendon material;
- collagen fiber;
- poly-L-lactic acid (PLLA);
- polylactic acid (PLA);
- polylactides (Pla);
- racemic form of polylactide (D,L-Pla);
- poly(L-lactide-co-D,L-lactide);
- polyglycolides (PGa);
- polyglycolic acid (PGA);
- polycaprolactone (PCL);
- polydioxanone (PDS);
- polyhydroxyacids; and

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resorbable plate material.

63. The prosthetic constraining kit of claim 62, wherein the extra cellular matrices (ECMs) include at least one of:

porcine small intestine submucosa (SIS);  
xenogeneic small intestine submucosa (xSIS);  
urinary bladder submucosa (UBS);  
laminated intestinal submucosa; and  
glutaraldehyde-treated bovine pericardium (GLBP).

64. The prosthetic constraining kit of claim 54, wherein a distal surface of at least one constraining augment is contoured to approximate the shape of a portion of the neck of the femoral member.

65. The prosthetic constraining kit of claim 54, wherein at least one constraining augment is positioned on the anterior/superior portion of the acetabular cup assembly.

66. The prosthetic constraining kit of claim 54, wherein at least one of the constraining augments has an inner radial surface that is substantially semi-spherically shaped to complement the shape of the femoral head of the femoral member.

67. The prosthetic constraining kit of claim 59, wherein the at least one fastener is an integrated fastener including snap-on retention members enabling snap-on mounting to the acetabular cup assembly.

68. The prosthetic constraining kit of claim 55, wherein the material of at least one of the constraining augments is supplemented with an agent to promote the formation of scar tissue.

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69. The prosthetic constraining kit of claim 55, wherein the material of at least one of the constraining augments is supplemented with a clotting agent.
70. The prosthetic constraining kit of claim 55, wherein the material of at least one of the constraining augments is supplemented with an antibacterial agent.
71. The prosthetic constraining kit of claim 54, wherein a distal surface of at least one of the constraining augments further includes an elevated portion for reducing angular movement of the femoral member in the radial direction of the elevated portion.
72. The prosthetic constraining kit of claim 71, wherein the elevated portion is located in a radially outer region of the constraining augment when mounted to one of the acetabular prosthesis and an area surrounding the acetabular cavity within the hip bone.
73. A constraining device for, at least temporarily, promoting engagement of a prosthetic femoral stem component with a prosthetic acetabular component of a prosthetic hip assembly, the constraining device comprising a semiannular segment of material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.
74. The constraining device of claim 73, wherein the semiannular segment of material includes at least one, or an equivalent, of:
- extra cellular matrices (ECMs);
  - poliglecaprone 25;
  - polydioxanone;
  - surgical gut suture (SGS);
  - gut;
  - polyglactin 910;
  - human autograft tendon material;
  - collagen fiber;

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poly-L-lactic acid (PLLA);  
polylactic acid (PLA);  
polylactides (Pla);  
racemic form of polylactide (D,L-Pla);  
poly(L-lactide-co-D,L-lactide);  
polyglycolides (PGa);  
polyglycolic acid (PGA);  
polycaprolactone (PCL);  
polydioxanone (PDS);  
polyhydroxyacids; and  
resorbable plate material.

75. The constraining device of claim 74, wherein the extra cellular matrices (ECMs) includes at least one of:

porcine small intestine submucosa (SIS);  
xenogeneic small intestine submucosa (xSIS);  
urinary bladder submucosa (UBS);  
laminated intestinal submucosa; and  
glutaraldehyde-treated bovine pericardium (GLBP).

76. The constraining device of claim 73, wherein the semiannular segment of material is molded in the form of a constraining ring adapted to be segmented and mounted to a rim of an acetabular cup assembly of the acetabular prosthesis component.

77. The constraining device of claim 73, wherein the semiannular segment of material is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.

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78. The constraining device of claim 77, wherein the semiannular segment of material is adapted to be substantially absorbed and replaced by scar tissue within approximately 6 months after implantation.

79. The constraining device of claim 73, wherein the semiannular segment of material is supplemented with an agent to promote the formation of scar tissue.

80. The constraining device of claim 73, wherein the semiannular segment of material is supplemented with a clotting agent.

81. The constraining device of claim 73, wherein the semiannular segment of material is supplemented with an antibacterial agent.

82. A restraining device for, at least temporarily, promoting engagement between at least two of a first prosthetic joint component, a second prosthetic joint component, a first bone component, and a second bone component, wherein the restraining device is comprised of a restraining material including at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials, wherein the restraining device does not circumscribe at least one of the first prosthetic joint component, the second prosthetic joint component, the first bone component, and the second bone component.

83. The restraining device of claim 82, wherein the restraining material includes at least one, or an equivalent, of:

- extra cellular matrices (ECMs);
- poliglecaprone 25;
- polydioxanone;
- surgical gut suture (SGS);
- gut;
- polyglactin 910;

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human autograft tendon material;  
collagen fiber;  
poly-L-lactic acid (PLLA);  
polylactic acid (PLA);  
polylactides (Pla);  
racemic form of polylactide (D,L-Pla);  
poly(L-lactide-co-D,L-lactide);  
polyglycolides (PGa);  
polyglycolic acid (PGA);  
polycaprolactone (PCL);  
polydioxanone (PDS);  
polyhydroxyacids; and  
resorbable plate material.

84. The restraining device of claim 83, wherein the extra cellular matrices (ECMs) includes at least one of:

porcine small intestine submucosa (SIS);  
xenogeneic small intestine submucosa (xSIS);  
urinary bladder submucosa (UBS);  
laminated intestinal submucosa; and  
glutaraldehyde-treated bovine pericardium (GLBP).

85. The restraining device of claim 82, wherein the restraining device is adapted to be mounted to at least one of the first prosthetic joint component, the second prosthetic joint component, the first bone component, and the second bone component.

86. The restraining device of claim 82, wherein the restraining device is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.

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87. The restraining device of claim 82, wherein the restraining material is adapted to be substantially absorbed and replaced by scar tissue within approximately 6 months after implantation.

88. The restraining device of claim 82, wherein the restraining material is supplemented with an agent to promote the formation of scar tissue.

89. The restraining device of claim 82, wherein the restraining material is supplemented with a clotting agent.

90. The restraining device of claim 82, wherein the restraining material is supplemented with an antibacterial agent.

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